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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------|------------------|
| 10/722,695  | 11/24/2003  | Joseph L. Wooters    | 22058-536 (AM101268)     | 8353             |
| 30623 7590 12/21/2006<br>MINTZ, LEVIN, COHN, FERRIS, GLOVSKY<br>AND POPEO, P.C.<br>ONE FINANCIAL CENTER<br>BOSTON, MA 02111 |             |                      | EXAMINER<br>ARCHIE, NINA |                  |
|   |             |                      | ART UNIT                 | PAPER NUMBER     |
|   |             |                      | 1645                     |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE  |             | MAIL DATE            | DELIVERY MODE            |                  |
| 31 DAYS   |             | 12/21/2006           | PAPER                    |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/722,695

Applicant(s)

WOOTERS ET AL.

Examiner

Nina A. Archie

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 38-67 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 38-61, drawn to method for treating or preventing a Chlamydia infection in a subject, classified in class 424 subclass 141.1
- II. Claims 62-67, drawn to method for treating a viral infection in a subject, classified in class 424 subclass 141.1

2. Inventions I and II are related in that they are both methods but distinct as clearly stated by their preambles. Invention I is directed to a method for treating or preventing a Chlamydia infection in a subject, the method comprising administering to a subject in need thereof an effective amount of a therapeutic agent that disrupts the interaction between cyclophilin and a cyclophilin binding partner. Invention II is drawn to method for treating a viral infection in a subject, the method comprising administering an effective amount of a therapeutic agent to a subject in need thereof, wherein said therapeutic agent disrupts the interaction between cyclophilin and a viral-derived polypeptide, thereby inhibiting the viral-based infection or reducing at least one symptom of the viral-based infection. Inventions I and II have different steps in their methods, different reagents, and achieve different goal. For example, Invention I is a method comprising administering to a subject in need thereof an effective amount of a therapeutic agent that disrupts the interaction between cyclophilin and a cyclophilin binding partner. Invention II is a method comprising administering an effective amount of a therapeutic agent to a subject in need thereof, wherein said therapeutic agent disrupts the interaction between cyclophilin and a viral-derived polypeptide, thereby inhibiting the viral-based infection or reducing at least one symptom of the viral-based infection. Invention I uses a therapeutic agent which is an antibody that is not reactive to a recombinant macrophage infectivity potentiator polypeptide to achieve treating or preventing a Chlamydia infection in a subject. Invention II uses a therapeutic agent, which is an antibody that is reactive to a viral-derived polypeptide to achieve treating a viral infection in a subject.

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Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

### **Election of Species**

If the Applicant elects Invention I, the Applicant is required to elect a single species of the claimed Invention I.

Species of therapeutic agent;

- 1) Antibody that binds to cyclophilin A
- 2) Antibody that binds to cyclophilin B
- 3) Antibody that binds to cyclophilin C
- 4) Antibody that binds to cyclophilin D
- 5) Antibody that binds to cyclophilin binding partner protein T776
- 6) Antibiotic, cyclosporine
- 7) Antibiotic, derivative of cyclosporine SD2 N1M811
- 8) Cyclophilin A
- 9) Cyclophilin B
- 10) Cyclophilin C
- 11) Cyclophilin D
- 12) binding partner protein T776

If the Applicant elects Invention II, the Applicant is required to elect a single combination of species of the claimed Invention II.

Species A-viral-based infection;

- 1) Hepatitis C virus
- 2) Dengue fever virus

Species B-therapeutic agent;

- 1) Antibody that binds to cyclophilin A
- 2) Antibody that binds to cyclophilin B

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- 3) Antibody that binds to cyclophilin C
- 4) Antibody that binds to cyclophilin D
- 5) Antibody that binds to viral-derived polypeptide hepatitis C virus core protein
- 7) Antibody that binds to viral-derived polypeptide hepatitis C protein E1
- 8) Antibody that binds to viral-derived polypeptide hepatitis C protein E2
- 9) Antibody that binds to viral-derived polypeptide hepatitis C protein P7
- 10) Antibody that binds to viral-derived polypeptide hepatitis C protein NS2
- 11) Antibody that binds to viral-derived polypeptide hepatitis C protein NS3
- 12) Antibody that binds to viral-derived polypeptide hepatitis C protein NS4A
- 13) Antibody that binds to viral-derived polypeptide hepatitis C protein NS4B
- 14) Antibody that binds to viral-derived polypeptide hepatitis C protein NS5A
- 15) Antibody that binds to viral-derived polypeptide hepatitis C protein NS5B

The species of therapeutic agents for Invention I and II are independent or distinct because the therapeutic agents consist of antibodies, protein, and an antibiotic which are all chemically and functionally different and require a separate search. The etiologies of the species of viral-based infections are different and require a separate search. (See MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for Invention I and II prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. To clarify, Applicant should elect a single species of therapeutic agent for Invention I and a single combination of species A and B for Invention II. Currently, claims 38, 41-43, 45, 47-49, 52-61 (Invention I) and claim 62 (Invention II) are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina Archie whose telephone number is 571-272-9938. The examiner can normally be reached on M-F 8:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Nina Archie

Patent Examiner

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PATRICIA A. DUFFY  
PRIMARY EXAMINER